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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,025	10/10/2001	Geert Maertens	2752-56	7266

23117 7590 04/09/2003

NIXON & VANDERHYE, PC
1100 N GLEBE ROAD
8TH FLOOR
ARLINGTON, VA 22201-4714

EXAMINER
LI, BAO Q

ART UNIT	PAPER NUMBER
1648	12

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/973,025	MAERTENS ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-99* is/are pending in the application.

4a) Of the above claim(s) *55,56 and 62-87* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-54,57-61 and 87-99* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *08,612,973* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☒ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3 &6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 49-99 are pending.

Election/Restrictions

1. Applicant's election with traverse of Group I, subgroup (b), claims 49-54, 57-61 and 87-99 in the scope of an isolated antibody against hepatitis C virus (HCV) E2 antigen in Paper Nos. 8 and 11 are acknowledged. The traversal is on the ground(s) that it would not be undue burden on the examiner for searching all claims filed in the application. This is not found persuasive because claimed inventions are directed to different monoclonal antibodies against different HCV antigenic proteins. Different HCV antigenic proteins are structurally and functionally different, which required different searches. For example, the search of HCV E1 does not need to search HCV E2 or core proteins. Furthermore, different antibodies raised against different antigens have different patenable weights, which constitute patenable distinct inventions. Searches for all patentable distinct inventions both in house and in commercial database constitute a serious burden for the Office and examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claims 49-54, 57-61 and 87-99 in the scope of an isolated monoclonal antibody against HCV E2 are considered before the examiner.

Applicants are reminded to amend the claims in the scope of an HCV E2 monoclonal antibody for reflecting the examination on the merits.

Information Disclosure Statement

2. The information disclosure statement filed 10/10/2001 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. In the instant case, the foreign patents did not have copies in the files. . It has been placed in the application file, but the information referred to therein has not been considered. Please prove the legible copies of all foreign patents on the list.

Priority

3. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

New matter

4. The amendment filed paper no. 4, 05/04/2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: In claims 87, 89-99, an isolated antibody of claim 50, wherein said at least one of E1 protein, an E2 protein and an E1/E2 complex is at least 80% to 99% pure. Applicant is required to cancel the new matter in the reply to this Office Action.

New matter Rejection

5. Claims 87, 89-99 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the amendment of claims 87, 89-99 read on an isolated antibody of claim 50, wherein said at least one of E1 protein, an E2 protein and an E1/E2 complex is at least 80% to 99% pure are not described in the original disclosure of the specification as it was original filed. Applicants are suggested to point out precisely the support of the amendment in the specification, as it was original filed or cancel the new matter to overcome the rejection.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 49-54, 57-61 and 87-99 are rejected under 35 U.S.C. 102(a) as being anticipated by Mehta et al. (US Patent No. 5,308,750A).

8. Regarding to claims 49 and 57-61, Mehta et al. disclosed an isolated monoclonal antibody and a kit comprising the monoclonal antibody (See claims 1-2 and 12), which specifically bind to Hepatitis C virus (HCV) E2/NS1 antigen by immunizing mice with the synthetic peptide of HCV E2/NS1 selected from amino acid residues of 600-720 or 643-683 to immunize the mice (See line 47-60 on col. 11). Regarding Claims 50-54 and 89-99, they belong to the product-by-process type claims. The MPEP discusses product-by -process claims in chapter 2100: Even though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by -process claim is the same as, or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process. See MPEP 2113. In the instance case, the patenbility of a monoclonal antibody is only depended on the epitope to which the claimed monoclonal antibody recognizes. Therefore, the claimed invention is anticipated by the cited reference.

9. Claims 49-54, 57-61 and 87-99 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaito et al (J. Gene. Virol. 1994, Vol. 75, pp. 1755-1760).

10. Regarding claims 49-52, Kaito et al. disclose four monoclonal antibodies specifically reacting with putative HCV envelope protein including E2/NS1, wherein the recombinant envelope protein was expressed by recombinant vaccinia virus vector (see lines 6-36 on page 1758). Regarding Claims 53-54 and 89-99, they belong to the product-by-process type claims. The MPEP discusses product-by -process claims in chapter 2100: Even though product-by process claims are limited by and defined by the process, determination of patentability is based

on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by -process claim is the same as, or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process. See MPEP 2113. In the instance case, the patenbility of a monoclonal antibody is only depended on the epitope to which the claimed monoclonal antibody recognizes. Therefore, the claimed invention is anticipated by the cited reference.

Claim Rejections - 35 USC § 102

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 49-54, 57-61 and 87-99 are rejected under 35 U.S.C. 102(e) as being anticipated by Wantanabe et al (US Patent No. 5/610,009A).

12. Regarding to claims 49-50 and 57-61, Watanabe et al. disclosed a kit containing an isolated antibody raised by using the fusion protein expressed by mammalian expression system or and it encodes HCV E2 region (See claim 5 and Fig. 6), which specifically bind to Hepatitis C virus (HCV) E2. Regarding Claims 51-54 and 89-99, they belong to the product-by-process type claims. The MPEP discusses product-by -process claims in chapter 2100: Even though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by -process claim is the same as, or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process. See MPEP 2113. In the instance case, the patenbility of a monoclonal

antibody is only depended on the epitope to which the claimed monoclonal antibody recognizes. Therefore, the claimed invention is anticipated by the cited reference.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 49-54, 57-61 and 87-99 are rejected under 35 U.S.C. 102(b) as being anticipated by Houghton et al (EP 0,388,232A1).

15. Houghton et al. teach many technique of using their disclosed HCV antigen polypeptide or epitope for generating a monoclonal antibody (See section of preparation of antibodies against HCV epitopes on pages 18-20) and monoclonal antibodies as well as a diagnostic kit comprising the monoclonal antibody against antigenic or antigen epitopes (Claims 1-13 and lines 8-27 on page 21). The antigen polypeptides are disclosed recombinant HCV polypeptide of E, NS1 (now it is named E2), NS2, NS3, NS4 and NS5. Particularly preferred comprising E and/or NS1, or subunits thereof (See line 30 on page 118 through line 6 of page 21, and lines 28-33 on page 17). Houghton et al. explicitly teach that these epitopes are explicitly disclosed as 5 to 100 amino acids in length. More typically, 50 amino acids in length, preferably a maximum of about 30 amino acids. It is usually desirable to select HCG sequences of at least about 10, 1, 15 amino acids, up to a maximal of about 20-25 amino acids. Houghton et al. also disclose many of these epitopes (See claim 10). In addition, Houghton et al. teach that the immunogenic polypeptides are generated by using both prokaryotic and eukaryotic expression vector, wherein the eukaryotic expression system is a yeast compatible vectors or mammalian expression vector (See lines 5-54 on page 23). The polypeptide can be purified less 50 to 90% pure (See lines 21-31 on page 10). Therefore, the claimed invention is anticipated by the cited reference.

16. Claims 49-54, 57-61 and 87-99 are rejected under 35 U.S.C. 102(b) as being anticipated by Houghton et al (GB 2,212,511A).

17. Houghton et al. teach many technique of using their disclosed HCV antigen polypeptide or epitope for generating a monoclonal antibody (See section of preparation of antibodies against HCV epitopes on pages 44-46) and monoclonal antibodies as well as a diagnostic kit comprising the monoclonal antibody an HCV epitope (Claims 18, 23-24, 26, section of II.I on pages 49-50, lines 14-17 on page 9, and lines 25-27 on page 166), wherein the isolate antigen polypeptides encoded by the cDNA are disclosed in Fig. 1-32 that includes the region of amino acids 400-660 encoding the E2 region (see lines 25 on page 35 through 17 on page 37). Houghton et al. also particularly point out that NS1 (now it is named E2) is more likely rise neutralizing antibodies like other flavivirus. (lines 5-15 on page 41). Houghton et al. explicitly teach that these epitopes are generally relative small, typically 8-10 amino acids or less in length. Fragments of as fell as 5 amino acids may characterize as an antigen region (See lines 19-25 on page 37). In addition, Houghton et al. teach that the immunogenic polypeptides are generated by using both prokaryotic and eukaryotic expression vector, wherein the eukaryotic expression system is a yeast compatible vectors or mammalian expression vector (See section of general methods on pages 62-66). The polypeptide can be purified less 50 to 90% pure (See lines 8-15 on page 22). Therefore, the claimed invention is anticipated by the cited reference.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James C. Housel

JAMES HOUSEL 4/7/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600